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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,269	10/18/1999	ULF LINDAHL	003300-589	7046

7590

09/20/2002

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/403,269	Applicant(s) LINDAHL ET AL.	
	Examiner David J. Steadman	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 26 August 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 103-112.

Claim(s) objected to: 25, 47, 67, 68 and 72-75.

Claim(s) rejected: 21-24, 26-46, 48-66, 69-71 and 76-102.

Claim(s) withdrawn from consideration: 8, 19 and 20.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

Claims 8 and 19-112 are pending in the application.

Claims 8, 19, and 20 remain withdrawn from consideration.

Claims 103-106 and 107-112 are in condition for allowance.

Claims 21-24, 26-46, 48-66, 69-71, and 76-102 stand finally rejected.

Claims 25, 47, 67, 68, and 72-75 are objected to as being dependent upon a rejected base claim.

1. Applicants' amendment to claims 37, 43, 59, 65, 80, 86, 94, and 107 in Paper No. 20, filed 08/26/02 is acknowledged and has been entered.
2. The request for reconsideration has been considered but does not place the claims in condition for allowance for the reasons discussed below.
3. In view of applicants' amendment to claims 37, 59, 80, 94, and 107, rejection of the claims under 35 U.S.C. 112, second paragraph, is withdrawn.
4. The written description rejection of claims 21-24, 26-46, 48-66, 69-71, 76-102, and 107 under 35 U.S.C. 112, first paragraph, is maintained. Applicants argue (beginning at page 7 of Paper No. 20) the specification (at page 13, lines 13-26) discloses structural characteristics of the polypeptides encoded by the claimed polynucleotides. Applicants argue the structures and function of the polypeptides encoded by the claimed polynucleotides is recited in the claims according to the Revised Interim Written Description Guidelines and these characteristics are sufficient for one of skill in the art to visualize or recognize the entire genus of polynucleotides. Applicants argue the examiner has not provided either factual evidence or sound scientific reasoning to support his position. Applicants argue they do not intend to claim polynucleotides encoding the recited polypeptide fragments, e.g., amino acids 1 to 45 of SEQ ID NO:13, having C5-epimerase activity, but claim polynucleotides encoding polypeptides comprising the recited fragments. Applicants' argument is not found persuasive. It is noted that applicants claims are not so limited to polynucleotides encoding polypeptides exhibiting the "structural characteristics" as disclosed at page 13, lines 13-26 of the specification. The examiner acknowledges sufficient written description, i.e.,

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description of defined structural and functional characteristics, of the polypeptides encoded by the claimed polynucleotides of, for example, claim 21 parts (e) and (f) and claim 65 parts (b), (c), and (g)-(j). As stated in a previous Office action, polynucleotides encoding a polypeptide *comprising* the fragments and homologs thereof of SEQ ID NO:12 or SEQ ID NO:13, e.g., parts (a)-(d) and parts (g)-(m) of SEQ ID NO:13, that have not been fully described in the specification. The Federal Circuit (*UC California v. Eli Lilly*, (43 USPQ2d 1398)) has said that a sufficient written description of a genus of DNAs may be achieved by a recitation of a representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, *which features constitute a substantial portion of the genus*. The recited structural features of the genus of claimed polynucleotides ~~do~~ not constitute a substantial portion of the genus as the remainder of the structure of a polypeptide with C5-epimerase activity encoded by the claimed polynucleotides is *completely undefined*. The recited fragments of, for example, parts (a)-(d) and (g)-(m) of claim 21 or parts (a) and (d)-(f) of claims 65 are highly unlikely to have C5-epimerase activity and the disclosure of the "structural characteristics" as stated at lines 13-26 of page 13 of the specification does not define the remaining structural features necessary for a polypeptide encoded by the members of the claimed genus of polynucleotides to be selected. Applicants' attention is drawn to the distinction between parts (e) and (f) of claim 21 and parts (b), (c), and (g)-(j) of claim 65 (which have not been rejected) in which the fragment of SEQ ID NO:12 or SEQ ID NO:13 has C5-epimerase activity by itself and parts (a)-(d) and (g)-(m) of claim 21 and parts (a) and (d)-(f) of claim 65 in which substantial additional undefined sequence is necessary to select a member of the genus of claimed polynucleotides. The rejection is maintained for the reasons of record and the reasons discussed above.

5. In view of applicants' amendment to claim 107 to limit the claims to those polynucleotides encoding polypeptides with glucuronyl C5-epimerase activity, the scope of enablement rejection under 35 U.S.C. 112, first paragraph, is withdrawn.

6. The scope of enablement rejection of claims 21-24, 26-46, 48-66, 69-71, and 76-102 under 35 U.S.C. 112, first paragraph, is maintained. Applicants argue the specification discloses sequence, critical

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residues, transmembrane region, and glycosylation patterns that are necessary for activity and demonstrate, by way of a working example, catalytic activity of the polypeptide of SEQ ID NO:13. Applicants argue the polynucleotide sequence of SEQ ID NO:12 encoding the C5-epimerase of SEQ ID NO:13 and recited fragments thereof have been disclosed and can be used to determine the presence and activity of an encoded polypeptide. Applicants argue that the entire scope of the claimed polynucleotides is enabled based on the analysis of *In re Wands*. Applicants argue the specification discloses assays for screening polypeptides having C5-epimerase activity encoded by the claimed polynucleotides and assert that such screening would be routine and would not require undue experimentation to make all claimed polynucleotides. Applicants argue the polynucleotide sequence of SEQ ID NO:12 encoding the C5-epimerase of SEQ ID NO:13 and recited fragments thereof have been disclosed and can be used to determine the presence and activity of an encoded polypeptide. Applicants argue that, given the sequences of SEQ ID NOs:12 and 13 and fragments thereof and screening assays, one of skill in the art would be able to make the entire scope of claimed polynucleotides. Applicants' argument is not found persuasive. The examiner acknowledges the disclosure of enzymatic assays for identifying polypeptides having C5-epimerase activity at pages 10 and 11 of the instant specification. However, one of skill in the art would recognize that the fragments of SEQ ID NO:13, e.g., as recited in parts (a)-(d) and (g)-(m) or a polypeptide encoded by the fragments of SEQ ID NO:12 as recited in parts (a) and (d)-(f) of claim 65, are highly unlikely to exhibit C5-epimerase activity. While the specification suggests three *potential* N-glycosylation sites that *may be* important for catalytic activity, there is no disclosure of the catalytic domain of SEQ ID NO:13 or the residues of the structure of SEQ ID NO:13 that are necessary for catalytic activity. There is no guidance in the specification that the polypeptide fragments of SEQ ID NO:13 as recited in parts (a)-(d) and (g)-(m) or a polypeptide encoded by the fragments of SEQ ID NO:12 as recited in parts (a) and (d)-(f) of claim 65 have C5-epimerase activity. Therefore, it is highly unpredictable that if such fragments were found within a larger polypeptide that the larger polypeptide would exhibit C5-epimerase activity. Furthermore, the specification provides no guidance or working examples to demonstrate that such fragments found within a larger polypeptide

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would exhibit C5-epimerase activity. Thus, even if a skilled artisan were to use a polynucleotide encoding the recited fragments to isolate other encoding polynucleotides by, for example, hybridization assay or PCR, a high degree of unpredictability remains as to whether such polynucleotides would encode polypeptides having C5-epimerase activity. Therefore, an undue amount of experimentation would be required to make the claimed polynucleotides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.


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PRIMARY EXAMINER
GROUP 1800
1605

